

	TECHNICAL SHEET	ENR/11/38 – Ind 1 – 05/10/16	
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PRODUCT : KIPIC HYPODERMIC NEEDLES FOR SINGLE USE

1. ADMINISTRATIVE INFORMATION CONCERNING THE COMPANY		
1.1	Name : Aesthetic Group	
1.2	Address : ZA La Gobette 60540 Puisieux Le Hauberger France	Phone : +33 03 44 74 19 95 Fax : +33 03 44 74 18 94 E-mail : info@aestheticgroup.fr Website : www.aestheticgroup.fr
1.3	Contact Materiovigilance : Jérôme Baptendier	Phone : +33 03 44 74 19 95 Fax : +33 03 44 74 18 94 E-mail : info@aestheticgroup.fr

2. INFORMATION ON THE DEVICE OR EQUIPMENT																																																																	
2.1	Common name: Hypodermic needles for single use																																																																
2.2	Tradename: Kipic™																																																																
2.3	Nomenclature code: UMDNS : 12-745 GMDN : 17180 HS Code: 9018 32 10																																																																
2.4	Code LPPR (if applicable) : N/A																																																																
2.5	DM class: IIa Applicable EU Directive: 93/42/CEE Number of the notified body: 0123 DM manufacturer: Zhejiang kindly medical devices Co., Ltd. Add: No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang Province,PRC																																																																
2.6	Description of the device: The Kipic ™ disposable sterile needles are designed for hypodermic injections especially for infusion of drugs and blood collection, treat fat deposits and cellulite, alopecia, skin rejuvenation, pain management, osteoarthritis They are available in different lengths and diameters. The needles consist of a straight cannula with bevel and a Luer Lock base.																																																																
2.7	Catalog references: <table><tr><th>Item code</th><th>Color code</th><th>External diameter (mm)</th><th>Diameter (Gauge)</th><th>Length (mm)</th></tr><tr><td>KIPIC25G42</td><td>Orange</td><td>0,50</td><td>25</td><td>42</td></tr><tr><td>KIPIC27G04</td><td>Grey</td><td>0,40</td><td>27</td><td>4</td></tr><tr><td>KIPIC27G13</td><td>Grey</td><td>0,40</td><td>27</td><td>13</td></tr><tr><td>KIPIC27G42</td><td>Grey</td><td>0,40</td><td>27</td><td>42</td></tr><tr><td>KIPIC30G04</td><td>Yellow</td><td>0,30</td><td>30</td><td>4</td></tr><tr><td>KIPIC30G13</td><td>Yellow</td><td>0,30</td><td>30</td><td>13</td></tr><tr><td>KIPIC30G25</td><td>Yellow</td><td>0,30</td><td>30</td><td>25</td></tr><tr><td>KIPIC32G04</td><td>Green</td><td>0,23</td><td>32</td><td>4</td></tr><tr><td>KIPIC32G08</td><td>Green</td><td>0,23</td><td>32</td><td>8</td></tr><tr><td>KIPIC32G13</td><td>Green</td><td>0,23</td><td>32</td><td>13</td></tr><tr><td>KIPIC33G04</td><td>Blue</td><td>0,20</td><td>33</td><td>4</td></tr></table>					Item code	Color code	External diameter (mm)	Diameter (Gauge)	Length (mm)	KIPIC25G42	Orange	0,50	25	42	KIPIC27G04	Grey	0,40	27	4	KIPIC27G13	Grey	0,40	27	13	KIPIC27G42	Grey	0,40	27	42	KIPIC30G04	Yellow	0,30	30	4	KIPIC30G13	Yellow	0,30	30	13	KIPIC30G25	Yellow	0,30	30	25	KIPIC32G04	Green	0,23	32	4	KIPIC32G08	Green	0,23	32	8	KIPIC32G13	Green	0,23	32	13	KIPIC33G04	Blue	0,20	33	4
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KIPIC33G08	Blue	0,20	33	8
KIPIC33G13	Blue	0,20	33	13

Packaging :

UCD (Control Unit): Blister of 1 piece

CDT (Multiple of the UCD): Boxes of 100 pieces

All the needles are equipped with a polypropylene transparent sterility protection tube. This tube protects the bevel of the needle so that it is not blunt and is suitable for ethylene oxide sterilization.

The needles are packaged in an individual medical grade bag, which guarantees the protection of the needle and the maintenance of the sterile condition.

Labelling :



2. Composition of the device and accessories:

8 THE CANNULA

Kipic[™] needles are made of medical grade 304 stainless steel. The steel used to make cannulas has been selected for its surgical quality and high resistance to corrosion. The oblique bevel, the thin wall as well as the anti-friction silicone treatment of the cannulas make it possible to minimize the pain of the patient during the penetration of the needle.

THE HUB

Kipic[™] needles consist of a translucent Luer Lock polypropylene base. This very strong material gives them a very high resistance. They are colored according to the ISO 6009 standard in force. The 6% Luer Lock fitting allows the use of Luer Lock accessories for better sealing and preventing disconnection.

Latex : **Présence** Absence

Phtalates (DHP) : **Présence** Absence

Product of animal or biological origin: **Présence** Absence

Associated devices and accessories: Hypodermic needles can be used with syringes and infusion / transfusion devices equipped with a Luer / Luer lock male connector.

2. Intended use :

9 Hypodermic needles are used with disposable syringes or disposable infusion / transfusion devices for infusion of drugs and blood collection. They are single-use can prevent infection between patients.

Indications :

- Injections into subcutaneous, intramuscular, intravenous, intravitreal, intra-articular and other soft tissues
- Blood collect
- Fine needle aspiration

3. STERILIZATION METHOD

DM sterile : YES ~~NO~~
Device Sterilization Mode: Ethylene Oxide

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4. CONDITIONS OF STORAGE AND STORAGE

The relative humidity for the product's storage location must not exceed 80% RH

5. SAFETY OF USE

5.1	Technical security: The MRI compatibility of our needles has not been tested Needle is X-ray detectable Like all stainless steel needles, steel could be altered by hydrochloric acid
5.2	Biological safety: Be careful to follow the usual aseptic procedures After use, handle and dispose of with other contaminated devices

6. ADVICE OF USE

6.1	Manual: N/A
6.2	Indications : Injections into subcutaneous, intramuscular, intravenous, intravitreal, intra-articular and other soft tissues Blood collect Fine needle aspiration
6.3	Precautions for use: - The product must not be reused. - Do not resterilize - Entrust the operation and use of the product and accessories only to persons with the required training, knowledge or experience. - Physicians administering drug therapy should be aware of the chemicals / medications injected, dosages, particular side effects and potential interactions. - Use the product only for the intended purpose, see Scope of application / see Contraindications. - Before each use, make a visual examination of the product: absence of loose, bent, broken, cracked, worn and broken parts. - Never use a damaged or defective product. Dispose of any damaged product immediately. - Check the integrity of the primary packaging before use. Never use this device when the primary packaging is damaged. - Do not use beyond the expiry date - Be very careful to apply the usual aseptic procedures due to the risk of infection - Do not exert excessive force that may cause the needle to break - Solutions based on hydrochloric acid can alter the steel - Check the integrity of the needle during removal - For single use only. Discard after use - After use, handle and dispose of contaminated devices - Do not recap - Use immediately after opening the packaging and avoid polluting.
6.4	Contraindications: Do not use if the patient is allergic to nickel

7. COMPLEMENTARY INFORMATION ON THE PRODUCT

N/A

8. ANNEXES

N/A

9. IMAGES

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